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1. Purpose/Policy

The purpose of this document is to define a coherent, unequivocal and systematic way of naming MDSAP records.

2. Scope

The naming convention specified in this procedure applies to the name of the electronic file in MDSAP record repository(ies).

This document is not to specify any record format or reference to the Auditing Organizations (AOs). For example, each AO may have their unique certificate identification system, generating certificate numbers of diverse formats.

3. Definitions/Acronyms

Facility ID - A facility's identification number generated by the Regulatory Exchange Platform – secure (REPs).

4. Authorities/Responsibilities

The assignment of the record identifier is under the responsibility of the following functions/entities:

- For the assessment documents: the Assessment Program Manager (APM)
- For the audit documents: the MDSAP Secretariat or MDSAP QMS Management Representative upon receipt of the record
- For the internal QMS records: the MDSAP QMS Management Representative.

5. Procedures

5.1 Format – General Concept

The principle of the naming convention is based on the assembly of concise and meaningful information in a specified order.

Each document will be named using the format **YYYY-MM-DD-*AAA*-(issuing AO identifier)-(Entity Identifier)-(NN)-(*A*NN).VVV**, where:

- YYYY-MM-DD is the most meaningful record date (refer to table below)
- A 3-letter code corresponding to the type of record (*AAA*)
- If applicable, the identifier of the AO issuing the record (AOID)
- If applicable, the identifier of the assessed or audited entity to which the record pertains (AOID for the assessed AO, or Facility ID for the audited manufacturer)
- A numerical chronological order (NN)
  (If two NCs are initiated the same day, then the date will not be sufficient to differentiate between the two. An additional key is necessary to differentiate the different records. Example: the first would be listed as NN=01, the second as NN=02 and so forth)
- A version number (VVV) (Example: 001=first version; 002=second version)

To distinguish between the identifier of the AO and of the manufacturer without ambiguity and make the reference more “user-friendly”, the manufacturer is identified by its Facility ID and the AO is identified by a 4-letter code based on the name of the AO. See Appendix 1 for codes assigned to each Auditing Organization authorized/recognized under the MDSAP.

Attachments to a record have the same name than the record it relates to, with an extension under the format –***A***NN and its specific version number. For example, the attachment #1 to report 2014-09-18-ASR-BSIA.001 could be 2014-09-18-ASR-BSIA-*A01.003*.

5.2 Format – Specifics

The table below lists the MDSAP records and their specific identifier format.

Records	Identifier Format	Date
Assessment Records		
Application	YYYY-MM-DD-*APP*-AOID.VVV	Receipt of the application
Notice of Change	YYYY-MM-DD-*NOC*-AOID.VVV	Receipt of the notice
Assessment Program Management File	YYYY-MM-DD-*APM*-AOID.VVV	Approval of the APM
Monitoring Report	YYYY-MM-DD-*MON*-AOID.VVV	Issue of the report
Assessment Plan	YYYY-MM-DD-*ASP*-AOID.VVV	1st day of the assessment
Assessment Report	YYYY-MM-DD-*ASR*-AOID(-Type).VVV[1]	1st day of the assessment
On Site Attendance	YYYY-MM-DD-*OSA*-AOID(-Type).VVV	1st day of the assessment
Witnessed Audit - Manufacturer Profile Form	YYYY-MM-DD-*MAN*-AOID-Facility ID.VVV	Receipt of the profile form
Witnessed Audit – Audit Plan	YYYY-MM-DD-*AUP*-AOID-Facility ID.VVV	1st day of the witnessed audit
Witnessed Audit Assessment Report	YYYY-MM-DD-*WIT*-AOID-Facility ID.VVV	1st day of the witnessed audit
AO Nonconformity Report	YYYY-MM-DD-*ANC*-AOID-NN.VVV	Issue of the NC
Technical Review	YYYY-MM-DD-*TER*-AOID.VVV	Review by the APM
Technical Review and Decision File	YYYY-MM-DD-*RAD*-AOID.VVV	Committee meeting
Authorization Letter	YYYY-MM-DD-*AUT*-AOID.VVV	Issue of the letter
Recognition Letter	YYYY-MM-DD-*REC*-AOID.VVV	Issue of the letter
AO Planning of Audit	YYYY-MM-DD-*PLA*-AOID.VVV	Receipt of the planning
Audit records		
Nonconformity Grading and Exchange Form	YYYY-MM-DD-*NGE*-AOID-Facility ID.VVV	Receipt of the document
Audit Reports	YYYY-MM-DD-*AUR*-AOID-Facility ID.VVV	1st day of the audit
Manufacturer Nonconformity Reports	YYYY-MM-DD-*MNC*-AOID-Facility ID-NN.VVV	Issue of the NC
Certification Document (i.e. certificate)	YYYY-MM-DD-*CER*-AOID-Facility ID-NN.VVV	Issue of the certificate
Internal QMS Documents		
Internal Audit Report	YYYY-MM-DD-*IAU*-RA[2].VVV	1st day of the audit
Concern Resolution Report	YYYY-MM-DD-*CRR*-NN.VVV	Initiation of the CRR
MDSAP Management Review	YYYY-MM-DD-*MMR*.VVV	Review meeting

6. Forms

- MDSAP QMS F0015.2 Checklist of Information to Provide by the Assessment ATL to the APM (optional)

[1] Assessment Report file name may be completed with an additional suffix for the assessment type (ST1 for Stage 1, ST2 for Stage 2, SU1 for Surveillance #1, RER for Re-recognition, SPR for Special Remote, SPO for Special On-Site)

[2] Internal Audit Report file name may be completed with the country of the Regulatory Authority audited (AUS for Australia, BRA for Brazil, CAN for Canada, JAP for Japan and USA for United States)

7. Reference Documents

- MDSAP QMS G0015.1 Box Directory File Structure for Assessment and Audit Records Guideline

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2014-02-10	Initial Release	Marc-Henri Winter
002	2015-06-09	Following types of records were included in the naming conventions: -Consolidation of several record types (RA nonconformity report, complaint and feedback, corrective action, and preventive action) into a single Concern Resolution Report (YYYY-MM-DD-CRR-NN.VVV) - See more detail on this consolidation with the creation of the Concern Resolution Procedure, superseding the Feedback and complaint, nonconformity, corrective and preventive action procedures) - Update of appendix: correction of AOs' information (name for BSI, Intertek, DUNS for Intertek and UL)	Marc-Henri Winter
003	2017-08-23	- Added the FDA MDSAP email address instead of the MDSAP Secretariat to the footer. - Updated version date and number Updated Appendix 1 in the following ways: Added NSF Health Science Certification; Removed LGA Intercert GmbH; Changed "SAI Global Certifications Ply Ltd.'s" name to "QMI-SAI Canada Limited." - Re-formatted in accordance with MDSAP QMS F0002.2 - Removed naming convention for RA Nonconformity Reports, Complaints and Feedback, Corrective Action, Preventive Action, which will be named as Concern Resolution Reports - Removed Assessment Team Recommendation naming convention - Included Technical Review, Authorization Letter and On Site Attendance naming convention - Changed the naming convention for Internal Audits	Andrew Durfor / Patricia Serpa
004	2021-02-08	- Updated project manager - Changed the Table of Contents - Added MDSAP QMS Management Representative to responsible party for audit records in section 4. - Replaced CMDCAS program with MDSAP in section 5.1 - - Added the section for Reference Documents - Updated Appendix 1; Added information of PRSF, MEDC, NCCB, Corrected information of GMED, , LRQA, ULAB, Removed NSFC - Replaced DUNS Number with Facility ID throughout the document	Hiromi Kumada/ Kimberly Lewandowski-Walker

Version 004
Approval

Approved: ON FILE Date: 2021-02-08
RAC Chair

Appendix 1:

Auditing Organizations' AOID Code

Auditing Organization	AOID Code
BSI Group America, Inc.	BSIA
DEKRA Certification B.V.	DEKR
DNV GL Presafe AS	PRSF
DQS Medizinprodukte GmbH	DQSM
Intertek Testing Services NA, Inc. (ITS)	ITSN
G-MED	GMED
Lloyd's Register Quality Assurance (LRQA)	LRQA
MedCert Zertifizierungs-und Prüfungsgessellschaft für die Medizin GmbH	MEDC
NCC Certificações do Brasil Ltda.	NCCB
National Standards Authority of Ireland (NSAI)	NSAI
QMI-SAI Canada Limited	SAIG
SGS United Kingdom Ltd.	SGSU
TÜV Rheinland of North America, Inc.	TUVR
TÜV SÜD America Inc.	TUVS
TUV USA, Inc.	TUVU
UL Medical and Regulatory Services, UL LLC	ULAB